

OCT 08 2010

510(k) Summary**510(k) SUMMARY**

This 510(k) Summary is provided per the requirements of section 807.92(c).

Owner Name: Bard Electrophysiology Division of C.R. Bard, Inc.

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Lowell, MA 01851

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Director, Regulatory Affairs

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Date of Summary: May 10, 2010

Device Trade Name: LabSystem™ PRO EP Recording System

Device Common Name: Programmable Diagnostic Computer

Classification Name: Programmable Diagnostic Computer

Predicate Device(s): Bard LabSystem PRO EP Recording System
(K031000/June 3, 2003)

Biosense Webster, Inc. CartoMerge Module of the Carto™
XP V8 EP Navigation System (K042999/March 21, 2005)

Device Description:

The LabSystem EP Recording System is a microprocessor based data acquisition system that is used during electrophysiology procedures to acquire ECG, intracardiac, pressure and digital data from other devices like fluoroscopic systems and RF generators. The ECG, intracardiac and pressure data are acquired by an amplifier that is connected to the patient.

Indications for Use:

The Bard LabSystem EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.

When integrated with the Philips EP navigator system, the BARD® LabSystem™ PRO EP Recording System is designed to acquire, analyze, and display 3D electro-anatomical maps of the human heart. The maps are constructed using intracardiac electrograms with their respective cardiac locations taken from live x-ray overlay on a patient's 3D cardiac anatomy. Maps may be displayed as electrical activation maps, voltage maps, dominant frequency maps and location maps with user defined measurement values.

Comparison to Predicate Devices:

The predicate devices for this 510(k) Premarket Notification are the LabSystem™ PRO EP Recording System (K031000) and the CartoMerge Module of the Carto™ XP V8 Navigation System (K042999).

The Indications for Use for both the LabSystem PRO EP Recording System V3.1 software and the CartoMerge Module of the CartoXP V8 EP Navigation System are

substantially equivalent as the CartoMerge Module of the CartoXP V8 Navigation System measurements are obtained in the same way as with the Bard LabSystem PRO EP Recording System V3.1 software. The two systems support activation timing, voltage amplitude, frequency measurements and location maps displayed on a segmented cardiac anatomy. Both Systems can acquire, analyze, and display 3D electroanatomical maps, construct maps using intracardiac electrograms with 3D cardiac positions, display color maps registered over patient's 3D cardiac anatomy, display electrical activation maps, display voltage maps, display dominant frequency maps, display location maps, and display user-defined measurement values. The generated electro-anatomical maps may be viewed in 3D on screen.

The hardware, base software and firmware that are currently utilized in the commercialized LabSystem PRO EP Recording System are identical to the LabSystem PRO EP Recording System with V3.1 software.

Summary of Non-Clinical Testing:

The LabSystem™ PRO EP Recording System is developed and produced in accordance with 21 CFR 820.30 Quality System Regulations. The software product is developed and tested in accordance with the following industry standards. Use of the IEEE standards is voluntary.

Substantial Equivalence:

The LabSystem™ PRO EP Recording System, subject of this 510(k), is substantially equivalent to the predicate devices. They have the same Indications for Use, principles of operation, materials of construction and the technological characteristics support a determination of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 08 2010

C.R. Bard, Inc.
Bard Electrophysiology Division
c/o Ms. Anastasia C. Randall
Regulatory Affairs Manager
55 Technology Drive
Lowell, MA 01851

Re: K101331
Trade/Device Name: LabSystem PRO EP Recording System V3.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: September 27, 2010
Received: September 28, 2010

Dear Ms. Randall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

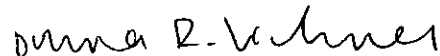
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K101331

Device Name: LabSystem™ PRO EP Recording System

Indications for Use:

V3.1 software for the LabSystem™ PRO EP Recording System Indication: The Bard LabSystem™ EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.

When integrated with the Philips EP navigator system, the BARD® LabSystem™ PRO EP Recording System is designed to acquire, analyze, and display 3D electro-anatomical maps of the human heart. The maps are constructed using intracardiac electrograms with their respective cardiac locations taken from live x-ray overlay on a patient's 3D cardiac anatomy. Maps may be displayed as electrical activation maps, voltage maps, dominant frequency maps and location maps with user defined measurement values.

Contraindications: None

Prescription Use X Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Dennis R. Johnson
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101331